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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/349,489 12/02/94 RING

D 0999.001

EXAMINER

HM22/0227

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INTELLECTUAL PROPERTY R440
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HUNT, J
ART UNIT PAPER NUMBER

1642
DATE MAILED:

02/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/349,489

Applicant(s)

RING

Examiner

Jennifer Hunt

Group Art Unit

1642

☒ Responsive to communication(s) filed on Dec 28, 1999

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-15 is/are pending in the application.

Of the above, claim(s) 4 and 9-14 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-3, 5-8, and 15 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Response to Amendment

1. Claims 1-15 are pending in the application. Claims 4 and 9-14 have been withdrawn from consideration as being drawn to a non-elected invention. Claims 1-3, 5-8, and 15 are under consideration.
2. This application contains claims 4 and 9-14 drawn to an invention nonelected without traverse in Paper No. 5. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Specification

3. The objection to the specification is withdrawn in light of the amendments thereto.

Claim Rejections Withdrawn

4. The rejection of claim 6 under 35 U.S.C. 112 second paragraph for the indefinite recitation of the term "glycolipid" is withdrawn in light of the deletion of the term.
5. The rejection of claims 1-3, 5-8, and 15 under 35 U.S.C. 102(a) as anticipated by Weiner et al. (Proc. Am. Soc. Clin. Oncol.13, March 1994) or Weiner et al. (Proc. Am. Soc. for Cancer Research, 35:219, March 1994) are withdrawn in light of applicant's declaration.
6. The rejection of claim 6 under 35 U.S.C. 112 first paragraph for failing to meet the description requirements is withdrawn in light of applicant's arguments and amendments thereto.

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Claim Rejections Maintained

7. The rejection of claims 1-3, 5-8, and 15 under 35 U.S.C. 103(a) as being unpatentable over Hsieh-Ma et al. (Cancer Research, 1992), Weiner et al., (Cancer Research 1993), or Ring et al., (Breast Epithelial Antigens, 1991), in view of Fanger et al. (Critical Reviews in Immunology, 1992) or Snider et al., (J. Exp. Med. 171:1957-1963, 1990) is maintained for reasons of record.

Applicant argues that the references fail to teach induction of an immune response in patients. Further, applicant argues that the declaration under in re Katz overcomes the rejection. Applicant's arguments filed 1-5-2000 have been fully considered but they are not persuasive.

As set forth in the previous Office Actions, and summarized herein for clarity, the references teach induction of an immune response in a patient, a xenograft mouse, which meets the limitation of the definition of patient as specified at page 8 of the instant disclosure. Although the references fail to teach an induction of antibody production to the second antigen (c-erb-B2), Fanger et al. teaches the known method comprising administering bispecific antibodies (and optionally antigen) to induce or enhance the production of antibodies targeted to the second antigen, and further that bispecific antibodies targeted to APC cell antigens induce production of antibodies to the second antigen.

With regard to the declaration, the declaration is not persuasive, because it is not sufficient to overcome the instant references cited, as the references were all published more than

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a year prior to the effective filing date of the instant application and thus are applicable as 102(b) dates, which cannot be overcome by a declaration. See MPEP 2133.02:

A rejection under 35 U.S.C. 102(b) cannot be overcome by affidavits and declarations under 37 CFR 1.131 (Rule 131 Declarations), foreign priority dates, or evidence that applicant himself invented the subject matter. Outside the 1-year grace period, applicant is barred from obtaining a patent containing any anticipated or obvious claims. In re Foster, 343 F.2d 980, 984, 145 USPQ 166, 170 (CCPA 1965).

8. The rejection of claim 6 under 112 first paragraph for lacking written description for failing to meet deposit requirements is maintained for reasons of record.

Applicant argues that the deposit requirements have been met, pointing to page 30 of the specification and a newly submitted declaration, however some required elements of the statement regarding deposit are missing (including address of the depository and assurance that should the deposit become non-viable, a substitute viable culture will be furnished). Thus the deposits fail to meet all the criteria set forth in MPEP 608/01 (p)(C), items 1-3. Assurance of compliance may be in the form of a declaration or averment under oath. A suggested format for such a declaration or averment is outlined below:

SUGGESTION FOR DEPOSIT OF BIOLOGICAL MATERIAL

A declaration by applicant, assignee, or applicant's agent identifying a deposit of biological material and averring the following may be sufficient to overcome an objection and rejection based on a lack of availability of biological material.

1. Identifies declarant.

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2. States that a deposit of the material has been made in a depository affording permanence of the deposit and ready accessibility thereto by the public if a patent is granted. The depository is to be identified by name and address.

3. States that the deposited material has been accorded a specific (recited) accession number.

4. States that all restrictions on the availability to the public of the material will be irrevocably removed upon the granting of a patent.

5. States that the material has been deposited under conditions that ensure that access to the material will be available during the pendency of the patent application to one determined by the Commissioner to be entitled thereto under 35 CFR 1.14 and 35 USC 122.

6. States that the deposited material will be stored with all care necessary to keep it viable and uncontaminated for a period of at least five years after the most recent request for the furnishing of a sample of the deposited microorganism, and in any case at least thirty (30) years after the date of a deposit or for the enforceable life of the patent, whichever is longer.

7. Acknowledges the duty to replace the deposit should the depository be unable to furnish a sample when requested due to the condition of the deposit.

8. That he/she declares further that all statements made therein of his/her own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

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Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, name and address of the depository, and the complete taxonomic description.

As a possible means of completing the record, applicants may submit a copy of the deposit receipt.

No claims are allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Hunt, whose telephone number is (703) 308-7548. The examiner can normally be reached Monday through Thursday 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached at (703) 308-3995. The fax number for the group is (703) 305-3014 or (703) 308-4242.


Communications via internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [anthony.caputa@uspto.gov].

All internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists the possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the group receptionist, whose telephone number is (703) 308-0196.

Jennifer Hunt

February 23, 2001


ANTHONY C. CAPUTA
SUPERVISOR, PATENT EXAMINER
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